510(k) Summary

Submitter:	Edwards Lifesciences LLC One Edwards Way Irvine, CA 92614-5686
Contact Person:	Daryl Richardson, Regulatory Affairs Associate III
Date Prepared:	July 18, 2008
Trade name:	Edwards Bovine Pericardial Patch
Classification Name:	Intracardiac Patch or Pledget (21 CFR 870.3470, Product Code DXZ)
Predicate Devices:	Edwards Bovine Pericardial Patch, K833763 PeriPatch™ Sheet, K040835 CV Peri-Guard Cardiovascular Patch, K971726 Glycar Pericardial Patch, K963967 Vascu-Guard, K942010
Device Description:	The Edwards Bovine Pericardial Patch is comprised of a rectangular sheet of bovine pericardium that has been preserved in a buffered glutaraldehyde solution. The pericardial patch is in the form of a 10 cm x 15 cm size, and may be tailored during surgery to meet the specific configuration needs of individual circumstances.
Indications for Use:	The Edwards Bovine Pericardial Patch is intended for use as a surgical patch material for: augmenting the patient's own pericardium to assist in closure following open-heart surgery; intracardiac defects; septal defects and annulus repairs; cardiac and vascular reconstruction and repairs; peripheral vascular reconstruction and repairs; great vessel reconstruction and repairs; and suture-line buttressing.
Comparative Analysis:	The Edwards Bovine Pericardial Patch is manufactured from glutaraldehyde fixed bovine pericardium; this is the same material used for the predicate devices. The Edwards Bovine Pericardial Patch is considered to be similar to the predicates because: • Same raw material • Same intended medical use • Operates using the same fundamental scientific technology • Similar shape • Similar processing method • Similar sterilization method • Similar packaging and labeling
Functional/Safety Testing:	The safety and effectiveness of bovine pericardial patches for reconstruction and repair is well established. Pericardial patches have been proven to be effective in achieving the desired result and well tolerated by the host tissue.
Conclusion:	The Edwards Bovine Pericardial Patch is substantially equivalent to the predicate devices.

OCT 23 2008

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 23 2008

Edwards Lifesciences LLC
c/o Mr. Daryl Richardson
Regulatory Affairs
Heart Valve Therapy
One Edwards Way
Irvine, CA 92614

Re: K082139
Edwards Bowine Pericardial Patch
Regulation Number: 21 CFR 870.3470
Regulation Name: Intracardiac Patch or Pledget
Regulatory Class: Class II
Product Code: DXZ
Dated: July 28, 2008
Received: July 29, 2008

Dear Mr. Richardson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at 240-276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number 800-638-2041 or 240-276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Edwards Lifesciences LLC
Traditional 510(k) Notification
Edwards Bovine Pericardial Patch, Model 4700

Indications for Use Statement

510(k) Number (if known): K082139

Device Name: Edwards Bovine Pericardial Patch

Indications for Use:

The pericardial patch is intended for use as a surgical patch material for: augmenting the patient's own pericardium to assist in closure following open-heart surgery; intracardiac defects; septal defects and annulus repairs; cardiac and vascular reconstruction and repairs; peripheral vascular reconstruction and repairs; great vessel reconstruction and repairs; and suture-line buttressing.

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Rodney

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K082139

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